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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,919	04/20/2004	Michael J. Adang	UGR-100XD1	6165

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EXAMINER	
LIU, SUE XU	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/828,919	ADANG ET AL.	
	Examiner	Art Unit	
	Sue Liu	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

Claims 5, 8, and 11 have been amended as filed on 7/21/06;

Claims 1-19 are currently pending.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, drawn to a polynucleotide that comprise a nucleotide sequence encoding an active toxin and a nucleotide sequence encoding a phage vector protein, classified variously, for example in class 536, subclass 23.4.

II. Claims 6-8, drawn to a polypeptide comprising a phage region and a toxin region, classified variously, for example in class 435, subclass 183+.

III. Claims 9-14 (NOTE: Claim 13 is dependent on itself), drawn to a method of preparing active Bacillus thuringiensis toxins, classified variously, for example in class 435, subclass 252.1+.

IV. Claims 15 and 16, drawn to a method of screening for novel Bt toxins, classified variously, for example in class 435, subclass DIG4.

V. Claim 17, drawn to a phage clone, classified variously, for example in class 435, subclass 235.1+.

VI. Claim 18, drawn to an isolated polynucleotide molecule, classified variously, for example in class 536, subclass 23.1.

VII. Claim 19, drawn to one or more plant cells, classified variously, for example in class 800, subclass 295+.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of Groups I, II, and V-VII are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, inventions of Groups I, II, and V-VII are drawn to distinct products because they differ in respect to their properties, their use and/or method of making. Group I is drawn to a polynucleotide molecule that comprises a toxin and a phage vector protein; Group II is drawn to a polypeptide molecule; Group V is drawn to a phage clone; Group VI is drawn to an isolated polynucleotide that encodes a toxin; Group VII is drawn to one or more plant cells. Group VII product of one or more plant cells require plant cells, which are not required by any other product groups. Group V product requires a phage clone that comprise a toxin, which are structurally and functionally different from the polynucleotide of Group I, and the polypeptide of Group II. Group I polynucleotide is structurally and functionally different from the Group II polypeptide. Art anticipating or rendering obvious each of the above identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics. Consequently, Groups I, II, and V-

VII have different issues regarding patentability and enablement and represent patentably distinct subject matter. Thus, restriction is proper.

3. Inventions of Groups III and IV are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case the different inventions in Groups III and IV direct to various distinct methods, because they use different steps, require different reagents and/or will produce different results. The invention of Group III directs to a method of preparing Bacillus thuringiensis toxins, and requires the step and/or reagent of "an active Bacillus thuringiensis" which is step and/or reagent that is not required by Group IV. Group IV method requires the step of screening for toxins and the reagent of a toxin specific target, which are steps and/or reagents that are not required by Group III. Consequently, Groups III and IV have different issues regarding patentability and enablement and represent patentably distinct subject matter. Thus, inventions of Groups III and IV are distinct, and restriction between the groups is proper.

4. Inventions of Groups (I, II, and V-VII) and (III and IV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of

using that product (MPEP § 806.05(h)). In the instant case, Groups (I, II, and V-VII) inventions drawn to polynucleotides, polypeptides, and phage clones, which can be used in different processes such as Groups III and IV methods. In addition, the products of Groups I, II, and V-VII can be used in and/or made by different processes from Groups III and IV methods. For example, the composition of Group I can be used as molecular marker, and Group II polypeptide can be used in antibody production. Thus, restriction between the groups is proper.

5. Therefore, these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter. Even though some of the groups are classified in the same class/subclass, this has no effect on the non-patent literature search. The different methods and products will require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches will be coextensive. Therefore, these do create an undue search burden, and restriction for examination purposes as indicated is proper.

Species Election

6. This application contains claims directed to the following patentably distinct species of the claimed invention. For the elected Group of invention, applicants are requested to further elect **a single ultimate species for <u>each</u>** of the following:

A.) A single specific polynucleotide molecule as specified by the followings:

i.) A single specific coding region for a single specific active toxin. Applicants are requested to specify the name of the encoded toxin and any corresponding SEQ ID Nos (e.g. SEQ ID Nos 7 and 8 corresponding to a single specific toxin).

ii.) A single specific coding region for a phage vector protein. Applicants are requested to specify the name of the phage vector protein and any corresponding SEQ ID Nos.

B.) A single specific polypeptide molecule that is encoded by the selected polynucleotide in A.) as specified by the followings:

i.) A single specific active toxin. Applicants are requested to specify the name of the toxin and any corresponding SEQ ID Nos.

ii.) A single specific phage vector protein. Applicants are requested to specify the name of the phage vector protein and any corresponding SEQ ID Nos.

C.) A single specific species of organism from which the selected toxin is derived from.

D.) A single specific species of phage display vector.

E.) A single specific type of cells to transform with the selected polynucleotide.

F.) A single specific species of a target to screen for a binding toxin.

The species are distinct, each from the other, because their structure and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter.

Therefore, this does create an undue search burden, and election for examination purpose as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1-19 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SL
Art Unit 1639
8/2/06

MARK SHIBUYA, PH.D.
PATENT EXAMINER